

Remarks

The above-identified application has been carefully reviewed in light of the Office Action mailed September 13, 2007.

Without conceding the correctness of any of the Examiner's rejections, applicant has amended the present claims in order to facilitate the prosecution of the above-identified application and obtain an early allowance. Applicant expressly reserves the right to seek patent protection for the original claims and all other claims supported by the above-identified application in one or more related applications.

Specifically, each of the present independent claims, that is each of claims 81, 194, 212, 214 and 218, has been amended to recite that the pocket created between a corneal epithelium of an eye and Bowman's membrane of the eye is created without creating an epithelial flap. This amendment is fully supported by the present specification, for example, at page 40, lines 8 to 20.

Claims 81-85, 89, 91, 92, 94-95, 97, 98, 105, 106, 108, 182, 183, 185, 188 and 191 have been rejected under 35 U.S.C. § 103(a) as being obvious over Perez WO 02/06883 (hereinafter Perez '883), in view of U.S. Pat. No. 5,171,318 (hereinafter Gibson) or U.S. Pat. No. 4,676,790 (hereinafter Kern). Claims 96, 100-102, 150, 178, 179, and 184 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson and Kern, as applied above, in further view of U.S. Pat. No. 4,959,353 (hereinafter Brown). Claims 121-123, 126, 132, 140, 160, 163, 164, 165, 166, 173, and 192 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson and Kern, as applied above, in further view of U.S. Pat. 6,335,006 (hereinafter Miller). Claims 112, 113, 124, 125, 134-137, 161, and 162 have been rejected under 35 U.S.C. § 103(a) as

being unpatentable over Perez '883, Gibson, Kern and Miller, as applied above, and further in view of U.S. Pub. No. 2003/0220653 (hereinafter Perez '653). Claim 171 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson, Kern and Miller, as applied above, and further in view of U.S. Pub. No. 2004/0015234 (hereinafter Peyman '234). Claim 177 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson, Kern and Miller, as applied above, and further in view of Brown. Claims 180, 192-196, 200-202, 206, and 209 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson and Kern, as applied above, in further view of U.S. Pat. No. 5,984,914 (hereinafter Cumming). Claim 211 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson, Kern and Cumming, as applied above, and further in view of U.S. Pat. No. 6,361,560 (hereinafter Nigam). Claim 107 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson and Kern as applied to claim 81 above, and further in view of Peyman '234. Claims 197 and 198 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson, Kern and Cumming, as applied to claim 194 above, and further in view of Perez '653. Claims 186 and 190 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson and Kern, as applied to claim 81 above, in view of U.S. Pub. No. 2002/0039788 (hereinafter Isseroff). Claims 203 and 208 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson, Kern and Cumming, as applied to claim 194 above, and further in view of Isseroff. Claim 210 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson, Kern and Cumming, as applied above to claim 194, and further in view of Brown. Claim 86 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883,

Gibson and Kern, as applied above, and further in view of U.S. Pat. No. 4,983,181 (hereinafter Civerchia). Claims 103 and 104 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson and Kern, as applied above, and further in view of Viegas U.S. Pat. No. 5,587,175 (hereinafter Viegas). Claims 212 and 213 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883 in view of Viegas. Claims 127-130, 167-170 and 214-221 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Perez '883, Gibson, Kern and Miller, as applied above, and further in view of Viegas.

Applicant traverses each of these rejections.

The presently claimed invention is directed to methods for vision correction.

In independent claim 81, the method comprises inserting a lens into a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and the Bowman's membrane of the eye wherein the lens is secured to the eye with an adhesive.

The method of independent claim 194 comprises cooling a corneal epithelium of an eye; and inserting a lens into a pocket created, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane of the eye, wherein the lens is secured to the eye with an adhesive.

The method of independent claim 212 comprises inserting a lens into a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye; and applying an effective amount of an epithelium preserving agent to the epithelium, wherein the epithelium preserving agent includes at least one cellulosic component.

The method of independent claim 214 comprises applying a liquid to a corneal epithelium of an eye, the liquid being

effective in loosening the epithelium substantially without killing epithelial cells; treating the epithelium to provide or maintain the epithelium in a moisturized state, wherein the treating step comprises applying a gel to the epithelium; raising a portion of the loosened, moisturized epithelium from Bowman's membrane of the eye; separating the raised portion of the epithelium from the Bowman's membrane; forming one or more incisions in the raised portion of the epithelium to create a pocket, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane; and inserting a lens into the pocket.

The method of independent claim 218 is similar to that of independent claim 214 except that the treating step is not specifically recited, and the one or more incisions in the raised portion of the epithelium to create a pocket, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane are one or more elongated incisions.

Each of the present claims recites a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye. Applicant has found that such a pocket can be created between the corneal epithelium and Bowman's membrane of an eye. Moreover, applicant has also found that such a pocket can be effectively used to insert a lens into the pocket in a method of correcting vision.

A pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of an eye is different and distinct from an epithelial flap. For example, such a pocket allows the insertion of a lens between the corneal epithelium of an eye and Bowman's membrane of an eye substantially without uncovering or exposing the anterior surface (Bowman's membrane) of the cornea. See Fig. 7A of the

above-identified application. This use of such a pocket is in direct contrast to lens insertion techniques that produce a flap of epithelial tissue, that is an epithelial flap, to expose or uncover an anterior surface of the cornea, as discussed in the present specification and as shown in Figs. 6A, 6B and 6C of the above-identified application. Uncovering and/or exposing the anterior surface of the cornea by forming an epithelial flap places the eye under increased stress and results in increased side effects and increased healing times, all to the detriment of the patient.

Applicant has found that inserting a lens in a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye provides substantial, surprising and unpredictable advantages relative to lens insertion techniques using an epithelial flap. For example, using such a pocket created without creating an epithelial flap allows the inserted lens to be effectively substantially fixedly positioned with respect to the eye, for example, by the epithelium. In addition, inserting a lens between the epithelium and Bowman's membrane through such a pocket, created without creating an epithelial flap, provides for relatively enhanced healing or reduced healing times and reduced side effects relative to methods that produce an epithelial flap to insert a lens. See page 39, line 16 to page 40, line 6 of the present specification.

The use of a pocket created, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane, as recited in the present claims, is in clear, direct and express contrast to the use of a flap which is often moved up and/or away to expose an interior eye surface during surgery. Advantageously, using a pocket created, without creating an epithelial flap, between a corneal epithelium and Bowman's

membrane of an eye allows the lens to be inserted substantially without exposing the portion of the cornea under or posterior to the corneal epithelium. Thus, using such a pocket avoids exposing a very sensitive part of the eye without the protective covering afforded by the corneal epithelium. Ultimately, a better overall outcome for the patient is likely using a pocket created, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane, as in the present invention, relative to lens insertion methods which involve forming an epithelial flap.

To establish a prima facie case of obviousness, among other criteria, the prior art reference (or references when combined) must teach or suggest all the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). Applicant will show, as set forth below, that none of the cited prior art references, taken alone or in any combination, teach or suggest all of the features recited in the present claims, including a pocket created, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane of an eye. Therefore, applicant submits that no prima facie case of obviousness can properly be maintained against the present claims.

Perez '883 discloses a lens placement procedure in which an epithelial flap is created, a lens is placed on the corneal stromal margin and then the epithelial flap placed over the epithelial flap. See Fig. 5 and page 19, lines 1-16 of Perez '883, specifically cited by the Examiner.

Perez '883 does not disclose, teach or suggest the present invention. For example, Perez '883 does not disclose, teach or even suggest a method of vision correction which comprises inserting a lens into a pocket created, without the creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as recited in the present claims.

Moreover, Perez '883 does not even suggest creating any pocket between the corneal epithelium and Bowman's membrane of an eye, let alone such a pocket without creating an epithelial flap.

The Examiner, citing the above-noted portions of Perez '883, states that Perez '883 teaches a method of creating a pocket between the epithelium layer of a cornea and the Bowman's membrane and then inserting a lens therein before closure thereof. Applicant vigorously disagrees with the Examiner's statement.

Perez '883 discloses the creation of an epithelial flap. Perez '883 does not disclose, teach or even suggest the creation of any pocket, much less the creation of a pocket, without creating an epithelial flap, as recited in the present claims. Perez '883 teaches creating an epithelial flap to allow placement of the lens. This is in clear, direct and express contrast to the present claims in which a pocket is created without creating an epithelial flap.

Perez '883 clearly and distinctly discloses and shows only an epithelial flap (608). In addition, Fig. 5 of Perez '633 shows the epithelial flap (608) lifted to expose and uncover the deepithelialized anterior surface of the cornea, the corneal stromal margin (612). The epithelial flap (608) of Perez '883 is substantially the same as the epithelial flap shown in Figs. 6A, 6B and 6C of the above-identified application, and is clearly distinguished from a pocket created, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane.

In addition, since Perez '883 does not disclose, teach or even suggest a pocket created, without creating an epithelial flap, between a corneal epithelium and Bowman's membrane of an eye, as recited in the present claims, Perez '883 does not suggest or even recognize the substantial and unexpected

advantages of using such a pocket. To reiterate, such a pocket allows lens insertion between the corneal epithelium and Bowman's membrane substantially without uncovering or exposing the anterior surface (Bowman's membrane) of the cornea. Such a pocket, without creating an epithelial flap, can provide enhanced healing or reduced healing times and reduced side effects relative to creating an epithelial flap, such as flap (608) of Perez '883, to insert a lens.

Simply put, the Examiner has no basis in fact, no other proper reasonable or rational basis and no common sense basis for contending that Perez '883 discloses, teaches or even suggests methods involving creating a pocket, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims. By emphasizing the need for an epithelial flap (608), Perez '883 teaches clearly, directly and expressly away from the present invention as recited in the present claims.

Further, Perez '883 does not disclose, teach or even suggest any of the present methods (1) in which a lens is secured to the eye with an adhesive, as in independent claims 81 and 194; or (2) including cooling a corneal epithelium of an eye, as in independent claim 194; (3) or applying an effective amount of an epithelium preserving agent including at least one cellulosic component, as in independent claim 212; or (4) including applying a liquid to a corneal epithelium of an eye to loosen the epithelium substantially without killing epithelial cells or using a gel or gel-containing composition or any of the other steps recited in independent claims 214 and 218.

Each of the 17 separate rejections presented by the Examiner is based on Perez '883 in combination with from 1 to 4 other references. Applicant will show that none of these other

prior art references supply the deficiencies apparent in the teachings of Perez '883.

Initially, the Examiner relies on Gibson or Kern in combination with Perez '883.

Gibson discloses implanting a contact lens in a cornea by removing a central portion of the epithelium, making an incision through Bowman's membrane into the stromal tissue and forming a continuous pocket in the stroma. Gibson discloses that the edge of the contact lens is placed into the stromal pocket, and that after lens insertion the surgeon inserts a small amount of tissue adhesive into the pocket.

Gibson does not disclose, teach or suggest the present invention. For example, Gibson, like Perez '883, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims. Gibson discloses removing epithelial tissue and forming a pocket in the stroma of an eye. Thus, Gibson actually teaches away from the present invention and methods involving creating a pocket, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane of an eye. That Gibson discloses using a tissue adhesive in a stromal pocket, in combination with the deficient teachings of Perez '883, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present invention, particularly in view of the substantial deficiencies of Gibson regarding the present claims, for example, as outlined above.

Kern discloses a process for implanting corneal inlays including laser milling to remove the corneal epithelium so that the surface of the implant will lay flush with Bowman's membrane. Kern discloses that collagen glue can be used to bond

the implant to the recessed portion of the cornea. Kern discloses that the implant is laser treated to promote/support re-growth of the epithelium.

Kern does not disclose, teach or suggest the present invention. For example, Kern does not even suggest a method involving creating any pocket, let alone methods involving creating a pocket, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane of an eye, as in all the present claims. Kern discloses laser milling the epithelium tissue to remove the corneal epithelium and recess the corneal surface to allow the inlay to be implanted. This is entirely different and distinct from the presently claimed methods.

To a large extent, by teaching removal of the corneal epithelium, Kern actually teaches away from the present claims. The fact that Kern discloses using collagen glue to bond an inlay to a laser milled, recessed corneal surface, in combination with the deficient teachings of Perez '883, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present claims, particularly in view of the substantial deficiencies of Kern regarding the present claims, for example, as outlined above.

In view of the above, applicant submits that all of the present claims, and in particular claims 81-85, 89, 91, 92, 94-95, 97, 98, 105, 106, 108, 182, 183, 185, 188 and 191, are unobvious from and patentable over Perez '883 in view of Gibson or Kern under 35 U.S.C. § 103(a).

Brown discloses promotion of corneal stroma wound healing with human epidermal growth factor prepared from recombinant DNA. Brown discloses utilizing a composition including a purified polypeptide having mitogenic activity capable of promoting the growth of both the epidermal and dermal layers of

the skin, as well as the epithelial and stromal layers of the cornea and other organs.

Brown does not disclose, teach or suggest the present invention. For example, Brown, like Perez '883, Gibson and Kern, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims. In fact, Brown does not even suggest creating any corneal pocket, let alone a pocket as recited in the present claims.

In view of the above, applicant submits that Brown does not supply the deficiencies apparent in Perez '883, Gibson and Kern, and, in addition, in combination with the deficient teachings of Perez '883, Gibson and Kern, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claims 96, 100-102, 150, 178, 179 and 184, are unobvious from and patentable over Perez '883, Gibson and Kern in further view of Brown under 35 U.S.C. § 103(a).

Miller discloses a method of delaminating the epithelial sheet of the cornea by loosening the epithelial sheet with a loosening solution, including an agent such as hyaluronidase ACS, and separating the loosened epithelial sheet from the underlying tissue of the cornea.

Miller does not disclose, teach or suggest the present invention. For example, Miller, like Perez '883, Gibson and Kern, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims. Miller does not even

suggest creating any corneal pocket, let alone a pocket as recited in the present claims.

In view of the above, applicant submits that Miller does not supply the deficiencies apparent in Perez '883, Gibson and Kern, and, in addition, in combination with the deficient teachings of Perez '883, Gibson and Kern, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claims 121-123, 126, 132, 140, 160, 163, 164, 165, 166, 173 and 192, are unobvious from and patentable over Perez '883, Gibson and Kern in further view of Miller under 35 U.S.C. § 103(a).

Perez '653 discloses preferred chemical compositions for epithelial delamination include vesicants such as 1M hypertonic saline, ethanol, cantharidin, and CEES.

As stated in the AMENDMENT IN RESPONSE TO FEBRUARY 3, 2006 OFFICE ACTION, on pages 16 of 21 and 17 of 21, the disclosure of Perez '653 regarding creating corneal epithelial pockets and use of non-donor corneal tissue lenses was added only after the effective filing date of the presently claimed subject matter. Therefore, Perez '653, with regard to such subject matter, is not prior art to the presently claimed invention.

As noted above, none of Perez '883, Gibson, Kern and Miller disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims.

The fact that Perez '653 discloses preferred compositions include vesicants such as 1 M hypertonic saline, ethanol, cantharidin, and CEES does not supply the deficiencies apparent

in Perez '883, Gibson, Kern and Miller. In addition, Perez '653, in combination with the deficient teachings of Perez '883, Gibson, Kern and Miller, provide no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claims 112, 113, 124, 125, 134-137, 161 and 162, are unobvious from and patentable over Perez '883, Gibson, Kern and Miller in further view of Perez '653 under 35 U.S.C. § 103(a).

Peyman '234 discloses using a microkeratome to form a flap in the surface of a cornea as part of a method to modify refractivity of a cornea of an eye with multiple inlays.

Peyman '234 does not disclose, teach or suggest the present invention. For example, Peyman '234, like Perez '883, Gibson, Kern and Miller, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims.

The disclosure and deficiencies of Brown have been discussed previously and are resubmitted here.

In view of the above, applicant submits that none of Peyman '234 and Brown, taken alone or in any combination, supply the deficiencies apparent in Perez '883, Gibson, Kern and Miller. None of these references, taken singly or in any combination, even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims. In addition, none of Peyman '234 and Brown, taken alone or in any combination, in combination with the deficient teachings of Perez '883, Gibson, Kern and Miller, provide any

motivation or any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claims 171 and 177, are unobvious from and patentable over Perez '883, Gibson, Kern and Miller in further view of one or more of Peyman '234 and Brown under 35 U.S.C. § 103(a).

For substantially similar reasons, applicant submits that the present claims, and in particular claim 107, are unobvious from and patentable over Perez '883, Gibson and Kern and further in view of Peyman '234 under 35 U.S.C. § 103(a).

Cumming discloses forming a pocket in a cornea of an eye so that at least one-half of the circumference remains intact throughout the corneal layers, thus leaving the cornea well supported, anteriorly by, Bowman's membrane and posteriorly by Descemet's membrane (column 2, lines 61-65). Thus, Cumming discloses that the pocket is formed in the stroma between the supporting structures of Bowman's membrane and Descemet's membrane. Cumming discloses that a tube or passage may be utilized to provide for air or gas passage therethrough from a pressurized source for the cooling of a spatula and areas being ablated, and for the removal and venting of debris or break down products of ablation.

Cumming does not disclose, teach or suggest the present invention. For example, Cumming, like Perez '883, Gibson and Kern, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims. Cumming teaches forming a pocket in the stroma and, at least to this extent, teaches away from a pocket created, without creating an epithelial flap,

between the corneal epithelium and Bowman's membrane of an eye. In addition, Cumming does not disclose, teach or suggest cooling the corneal epithelium, as recited in certain of the present claims.

Moreover, the fact that Cumming discloses a pocket formed in the stroma of an eye in no way makes obvious a pocket created, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane, as recited in the present claims. For example, while the stroma, the middle layer of the cornea, is about 450 micrometers thick (90% of the about 500 microns, the total thickness of the cornea - as disclosed at page 13, lines 4-10 of the present specification), the corneal epithelium, the anterior-most 5-6 cell deep layer of the cornea, is only approximately 50 micrometers thick. See page 12, lines 27-28 of the present specification.

The substantial differences, for example, in position, thickness and tissue composition, between the stroma and the corneal epithelium render forming a pocket in the stroma not even suggestive of forming a pocket between the corneal epithelium and Bowman's membrane, without creating an epithelial flap, as recited in the present claims. Because of such differences between the stroma and the corneal epithelium, it is much more technically challenging to form a pocket between the corneal epithelium and Bowman's membrane, without creating an epithelial flap, than it is to form a pocket in the stroma.

Thus, one of ordinary skill in the art would not reasonably expect that the teachings of a reference (e.g., Cumming) which discloses forming a pocket in the stroma would be useful in, or even be considered when, forming a pocket between the corneal epithelium and Bowman's membrane without creating an epithelial flap. This is particularly true since the tools used to make the pocket in the stroma have different physical and functional

parameters to remove more tissue, different tissue and differently positioned tissue than the tissue removed to create a pocket, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane. The pocket in the stroma of Cumming is not even suggestive of the pocket created, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane of an eye, as recited in the present claims.

In short, Cumming fails to supply the deficiencies apparent in the teachings of Perez '883, Gibson and Kern, and, in addition, in combination with the deficient teachings of Perez '883, Gibson and Kern, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claims 180, 192-196, 200-202, 206 and 209, are unobvious from and patentable over Perez '883, Gibson and Kern in further view of Cumming under 35 U.S.C. § 103(a).

Nigam discloses that implants, such as solid and split-ring shaped, circular flexible body members and other types of adjustable ring-shaped devices, can be implanted within the body of the cornea for changing the shape of the cornea, thereby altering the refractive power of the cornea. Nigam discloses that such prostheses typically are implanted by first making a tunnel and/or pocket within the cornea which leaves Bowman's membrane intact and does not relieve the inherent natural tension of the membrane. Nigam discloses placing a biocompatible, permeable, micro-porous hydrogel having a refractive index similar to the cornea by first creating a corneal flap, for example, using a microkeratome, to relieve tension of Bowman's membrane.

Nigam does not disclose, teach or suggest the present invention. For example, Nigam, like Perez '883, Gibson, Kern and Cumming, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims. Nigam does not disclose using a microkeratome to make any corneal pocket, let alone a pocket, without creating an epithelial flap, between a corneal epithelium and Bowman's membrane of an eye. Nigam discloses using a microkeratome to make a corneal flap. As noted above, such flaps are different and distinct from a pocket, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane of an eye, as in the present claims.

In view of the above, applicant submits that Nigam does not supply the deficiencies apparent in Perez '883, Gibson, Kern and Cumming, and, in addition, in combination with the deficient teachings of Perez '883, Gibson, Kern and Cumming, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claim 211, are unobvious from and patentable over Perez '883, Gibson, Kern and Cumming in further view of Nigam under 35 U.S.C. § 103(a).

The disclosure and deficiencies of Perez '653 have been discussed previously and are resubmitted here.

The Examiner takes the position that claims 197 and 198 are obvious contending that it would have been obvious to utilize a hypertonic solution in Perez '883 for the same reasons that Perez '653 utilizes the same and in order to prevent the use of

toxic residues to the eye tissue that cause toxicity problems after surgery. Applicant vigorously disagrees.

As noted above, Perez '883 does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all of the present claims. As noted previously, the disclosure of Perez '653 regarding creating corneal epithelial pockets is not prior art with regard to the presently claimed invention. Further, as noted above, none of Gibson, Kern and Cumming disclose, teach or even suggest any method which involves such a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye.

Thus, Perez '653 does not supply the deficiencies apparent in the teachings of Perez '883, Gibson, Kern and Cumming and, in addition, in combination with the deficient teachings of Perez '883, Gibson, Kern and Cumming, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 197 and 198, are unobvious from and patentable over Perez '883, Gibson, Kern and Cumming in view of Perez '653 under 35 U.S.C. § 103(a).

Isseroff discloses a bioengineered composite graft for the treatment of a damaged or diseased corneal epithelial surface. Isseroff discloses that the composite graft includes an extracellular carrier material including collagen.

Isseroff does not disclose, teach or suggest the present invention. For example, Isseroff, like Perez '883, Gibson, Kern and Cumming, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial

flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims. Isseroff discloses treating damaged or diseased corneal epithelial surfaces, rather than placing a lens in a pocket created between a corneal epithelium and Bowman's membrane of an eye.

In view of the above, applicant submits that Isseroff does not supply the deficiencies apparent in Perez '883, Gibson, Kern and Cumming and, in addition, in combination with the deficient teachings of Perez '883, Gibson, Kern and Cumming, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claims 186 and 190, are unobvious from and patentable over Perez '883, Gibson and Kern in further view of Isseroff under 35 U.S.C. § 103(a). Further, applicant submits that the present claims, and in particular claims 203 and 208 are unobvious from and patentable over Perez '883, Gibson, Kern and Cumming in further view of Isseroff under 35 U.S.C. § 103(a).

As noted previously, none of Perez '883, Gibson, Kern, Cumming and Brown disclose, teach or suggest the present invention. For example, none of these references even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all the present claims.

In view of the above, applicant submits that Brown does not supply the deficiencies apparent in Perez '883, Gibson, Kern and Cumming, and, in addition, in combination with the deficient teachings of Perez '883, Gibson, Kern and Cumming, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular, claim 210, are unobvious from and patentable over Perez '883, Gibson, Kern and Cumming in further view of Brown under 35 U.S.C. § 103(a).

Civerchia discloses a surgical method for placing an artificial lens in an eye which includes a first step of removing a portion of corneal epithelium from Bowman's membrane on an area slightly larger than the shape of the lens, for example, a collagen-hydrogel lens. Civerchia discloses that during the healing process the corneal epithelium grows over the lens. Civerchia discloses that the artificial lens can be removed and replaced by stripping the lens from Bowman's membrane and allowing corneal epithelium to grow over the defect, or a new collagen-hydrogel can be placed which will support re-growth of corneal epithelium.

Civerchia does not disclose, teach or suggest the present invention, for example, Civerchia, like Perez '883, Gibson and Kern, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as recited in all the present claims. The fact that Civerchia discloses removing and stripping the corneal epithelium from Bowman's membrane and re-growing the epithelium, actually teaches away from creating a pocket, without creating an epithelial flap, between the corneal epithelium and Bowman's membrane.

In view of the above, applicant submits that Civerchia does not supply the deficiencies apparent in Perez '883, Gibson and Kern, and, in addition, in combination with the deficient teachings of Perez '883, Gibson and Kern, provides no motivation nor any other reasonable or rational basis and no common sense

basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claim 86, are unobvious from and patentable over Perez '883, Gibson and Kern and in further view of Civerchia under 35 U.S.C. § 103(a).

Viegas discloses gels as protective corneal shields; or as ablatale corneal masks useful in laser reprofiling of the cornea. Viegas discloses that such gels include film-forming polymers, such as hydroxalkyl cellulosics, methyl celluloses, sodium hyaluronate and polyvinyl alcohol, which have been found useful in ophthalmic applications.

Viegas does not disclose, teach or even suggest the present invention. For example, Viegas, like Perez '883, Gibson, Kern and Miller, does not disclose, teach or even suggest any method which involves a pocket created, without creating an epithelial flap, between a corneal epithelium of an eye and Bowman's membrane of the eye, as in all of the present claims. In fact, Viegas does not even suggest creating any corneal pocket, let alone a corneal pocket as recited in the present claims.

In view of the above, applicant submits that Viegas does not supply the deficiencies apparent in Perez '883, Gibson, Kern and Miller, and, in addition, in combination with the deficient teachings of Perez '883, Gibson, Kern and Miller, provides no motivation nor any other reasonable or rational basis and no common sense basis for making obvious the present methods, as recited in the present claims.

Therefore, applicant submits that the present claims, and in particular claims 103 and 104, are unobvious from and patentable over Perez '883, Gibson and Kern in further view of Viegas under 35 U.S.C. § 103(a). In addition, applicant submits that the present claims, and in particular claims 212 and 213

are unobvious from and patentable over Perez '883 in view of Viegas under 35 U.S.C. § 103(a). Further, applicant submits that the present claims, and in particular claims 127-130, 167-170 and 214-221, are unobvious from and patentable over Perez '883, Gibson, Kern and Miller in further view of Viegas under 35 U.S.C. § 103(a).

Each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art, taken singly or in any combination, disclose, teach or even suggest the present methods including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are unobvious from and patentable over the prior art under 35 U.S.C. § 103(a). Therefore, applicant submits that claims 81-86, 89, 91-98, 100-108, 112, 113, 121-130, 132, 134-137, 140, 150, 160-171, 173, 177-180, 182-186, 188, 190-198, 200-203, 206 and 208-221 are allowable. Thus, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call applicant's attorney at the telephone number given below.

Respectfully submitted,



Date: 12/13/07

Frank J. Uxa
Attorney for Applicant
Registration No. 25,612
4 Venture, Suite 300
Irvine, California 92618
(949) 450-1750
(949) 450-1764 Facsimile